# United States Court of Appeals for the Federal Circuit

2015-1149

**LIFESCAN SCOTLAND, LTD.,**

*Appellant,*

v.

**PHARMATECH SOLUTIONS, INC.,**

*Appellee.*

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in No. IPR2013-00247

## REPLY BRIEF OF APPELLANT

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## CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, Counsel for Appellant certifies the following:

1. The full name of every party or amicus represented by me is:

LifeScan Scotland, Ltd.

2. The name of the real party-in-interest (if the party named in the caption is not the real party in interest) represented by me is:

LifeScan Scotland, Ltd.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Diabetes Diagnostics, Inc.; LifeScan, Inc.; Johnson & Johnson.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

AKIN GUMP STRAUSS HAUER & FELD LLP: Dianne B. Elderkin, Steven D. Maslowski and Jason E. Weil

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Dated: July 6, 2015

By: */s/ Dianne B. Elderkin*
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## INTRODUCTION

To decide this Appeal, the Court need look no further than the evidence Pharmatech failed to produce. Pharmatech bore the burden to prove LifeScan's patent invalid. It was required to introduce the evidence necessary to do so. But Pharmatech proffered, at best, only conclusory expert statements about the reference disclosures and motivation to combine those teachings. On the sparse record before it, the Board treated the IPR as an examinational proceeding, rather than the adjudicative proceeding it is meant to be. It resorted to finding "facts" never advanced by Pharmatech that were unsupported or even contradicted by the record, and it erroneously shifted the burden of proof to LifeScan.

In addition, the Board erred in its nexus analysis and accordingly failed to credit and give weight to Pharmatech's admission that it copied the test strips disclosed in the '105 Patent so that they could be sold for use with LifeScan meters to carry out the method claimed in the '105 Patent.

The Board's Final Written Decision is replete with legal errors, and its conclusion that the '105 Patent claims are obvious lacks substantial evidentiary support. The decision should be reversed.

Moreover, the IPR proceeding was procedurally flawed, having been initiated by persons not authorized to do so under the relevant statutes. Contrary to Pharmatech's and the USPTO's arguments, LifeScan did not waive, and this Court

has jurisdiction to decide, LifeScan's challenge to the lawfulness of the procedures by which the Board came to its decision. For this independent reason, the Court should reverse the Board's decision.

## ARGUMENT

### I. THE BOARD ERRED IN FINDING THAT PHARMATECH MET ITS BURDEN OF PROOF

As discussed in LifeScan's opening brief ("Br."), Pharmatech failed to meet its burden of proving that the invention claimed in the '105 Patent would have been obvious to one skilled in the art. The Nankai, Winarta and Schulman references lack key features of the '105 Patent claims, and the record is devoid of evidence that persons of skill in the art would have understood the references to suggest those features or would have been motivated to combine those references. Moreover, the Board erred in not crediting evidence of admitted copying. Pharmatech failed to meet its burden of proving invalidity of the '105 Patent claims, and the Board's decision should be reversed.

#### A. Nankai Does Not Suggest The Claimed Test Strip Configuration

The '105 Patent claims require use of a disposable test strip that has a reference electrode upstream from the two working electrodes. The working electrodes are used to take two independent measurements of the concentration of a substance (such as glucose) in a sample. The claimed upstream-reference

electrode configuration is crucial for detecting inaccurate blood glucose readings that can arise from applying insufficient blood sample to the strip. A1561-62.

The Board acknowledged that Nankai does not disclose the claimed configuration of electrodes. A11. Specifically, Nankai's reference electrode is *downstream*, not upstream, from working electrodes, and Nankai's configuration does not provide the benefits of the claimed invention.

No substantial evidence supports the Board's finding that it was obvious to alter Nankai to move the reference electrode upstream. That finding was based on the conclusory statements of Pharmatech's declarant Dr. Wang. A19 (citing A509 (¶25)). But such conclusory statements do not provide substantial evidentiary support for the Board's finding. *See Koito Mfg. Co. v. Turn-Key-Tech., LLC,* 381 F.3d 1142, 1152 (Fed. Cir. 2004) ("[g]eneral and conclusory testimony … does not suffice as substantial evidence of invalidity").

Pharmatech cannot point to anything in Dr. Wang's testimony about Nankai that was more than conclusory. Instead, it now argues that expert testimony is not needed to show that it would have been obvious to one skilled in the art to change Nankai's electrode arrangement by moving the reference electrode upstream (Ptech Br. at 48). To be sure, expert testimony may not be needed where technology is "easily understandable." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1240, 1242 (Fed. Cir. 2010). That was the situation in the cases Pharmatech cites, where the

technology relates to hitch pin locks and bulk e-mail distribution. *See id.*; *see also Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324 (Fed. Cir. 2009) (person of ordinary skill had a high school diploma, one year of relevant experience, and proficiency with computers and email programs).

However, this Court has made it clear that expert testimony is critical to establish obviousness where the subject matter is sufficiently complex to fall beyond the grasp of an ordinary layperson. *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1267 (Fed. Cir. 2008) (device for calibrating drug delivery devices); *Centricut, LLC v. Esab Grp., Inc.*, 390 F.3d 1361, 1363, 1370 (Fed. Cir. 2004) (electrodes used in plasma arc torches); *Koito*, 381 F.3d at 1152 n.4 (method of strengthening injection molded plastics). There is nothing simple about the electrochemical glucose measurement methods and sensors disclosed and claimed in the '105 Patent. The complexity of the technology is evident from the Board's definition of one of ordinary skill in the art as one having a Bachelor's degree in chemistry or electrical engineering or a related field and five years of experience working in the field of electrochemical sensors. A8.

Here, Pharmatech presented—and the Board expressly relied upon—expert testimony by Dr. Wang regarding the Nankai disclosure. A10, A19. As LifeScan explained, that testimony was hindsight-based, conclusory, and not presented from the standpoint of one of ordinary skill in the art (Br. at 41). Dr. Wang's testimony

is not supported by Nankai's disclosure or anything else. The testimony is plainly insufficient as evidence of obviousness, and the Board erred in relying on it.

Pharmatech argues that further evidence was unnecessary because the distinction between Nankai and the claimed invention is allegedly "merely the arrangement of three sensors," and it now proposes a series of alleged "[l]ogical arrangements" that are not mentioned anywhere in the record (Ptech Br. at 47-48). But the arrangement of sensors that the '105 patent discloses and claims is *critical* to the invention, not an arbitrary rearrangement of parts. As Dr. Smith explained:

> I disagree that "there is no criticality in arranging the reference electrode upstream," as argued by Pharmatech. Since the reference electrode in Nankai is placed downstream of the working electrodes, when insufficient blood is applied, the electrode that would be incompletely covered would be the reference electrode rather than a working electrode. Coverage of a minor portion of the reference electrode could cause a higher than normal current density to flow in the covered part of the electrode, altering the ability of the reference electrode to provide a stable potential against which the working electrode could be established and potentially causing inaccurate measurements of glucose. Nankai would not detect an inaccurate measurement made at any one of, or all of, the working electrodes; it would merely average the inaccurate measurement(s). Nankai does not recognize the criticality of placing the reference electrode upstream from the working electrode for obtaining accurate measurements.

A1561-62 (¶43).

Pharmatech does not cite, and the Board did not identify, anything in the record suggesting that the arrangement of the sensors was arbitrary or that the upstream location of the reference electrode would have been obvious. The Board

erred in disregarding Dr. Smith's testimony regarding the criticality of the claimed electrode arrangement. It also erred, in light of Dr. Smith's testimony, in characterizing, as "unrebutted testimony," Dr. Wang's conclusory statement that the arrangement of the Nankai electrodes may vary. A19.

As Pharmatech notes, the Board cited *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990), for the proposition that criticality must relate to an unexpected result. But as LifeScan explained (Br. at 43), *Woodruff* and its progeny are limited to inapposite situations in which the claims recite a numerical range that is encompassed within a range disclosed in the art. Pharmatech argues that *Woodruff* is not limited to instances of numerical ranges, but it does not cite—and our research has not disclosed—a single case where that proposition has been applied outside of that context. In fact, the single case Pharmatech cites on the issue (which involved a numerical range) refers to *Woodruff* and similar cases as "range cases." *Iron Grip Barbell Co. v. USA Sports, Inc*., 392 F.3d 1317, 1322 (Fed. Cir. 2004).[1]

This is not a situation where there are a finite number of alternatives achieving nothing more than predictable results. There is not a shred of record

[1] In *Iron Grip*, the prior art disclosed barbells with one, two, or four-hole weight plates. The patent claimed a barbell with three-hole weight plates, "within the range of the prior art." 392 F.3d at 1322.

evidence showing that the advantages of the claimed upstream reference sensor placement were predictable.

Pharmatech has no real response to LifeScan's showing that Dr. Wang's opinion was tainted by his hindsight reliance on the disclosure of the '105 Patent (Br. at 42). It relies on Dr. Wang's reference to a general statement in Nankai that the shape and arrangement of electrodes "may vary" (Ptech Br. at 47). A509 (¶25). But Nankai does not teach or suggest the specific arrangement that the '105 patent discloses and claims. And Dr. Wang's reliance on the vague statement in Nankai is based on an improper hindsight reference to the '105 Patent disclosure. A509 (¶25).

It is undisputed that Nankai does not disclose the specific electrode arrangement required by the '105 Patent claims. A11. This particular arrangement is critical for achieving one of the inventive goals of the '105 Patent, namely, providing an arrangement "whereby ... detection of inadequate fill and of defects in the working sensor part" can be obtained. A1565 (¶48) (quoting A62 (2:51-55)). Pharmatech failed to introduce substantial evidence that could support the Board's finding that the test strip elements of the '105 Patent claims would have been obvious from Nankai.

### B. Winarta Does Not Suggest The Claimed Test Strip Configuration

The Board also erred in its treatment of the Winarta reference.

The '105 Patent claims require both that there be a second working electrode *and* that a measurement of the electric current proportional to the concentration of substance (glucose) in a sample be made at that second working electrode. *See* A64-65 (6:52-8:5) ("a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid," and "measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid").

As LifeScan demonstrated, Winarta only discloses a single working electrode (Br. at 45). The second Winarta electrode, the "pseudo electrode" $W_0$, is disclosed as useful only as a trigger, as a counter electrode, or to measure resistance. A262 (5:63-6:10); A1567 (¶51). Winarta does not disclose $W_0$ as a working electrode for measuring the concentration of glucose.

Pharmatech concedes this (Ptech Br. at 59). The Board's obviousness conclusion rests entirely on its erroneous finding that Winarta's $W_0$ electrode is nonetheless "capable" of making a glucose measurement. But the question for obviousness is not whether persons skilled in the art *could* have used the $W_0$

electrode to measure glucose, it is whether they *would* have done so. And Pharmatech proffered no evidence on this point.

As LifeScan explained, the stated support for the Board's finding that the $W_0$ electrode is capable of making a glucose measurement was Dr. Wang's testimony that Winarta is "capable of taking multiple measurements" (Br. at 45). That statement was not supported by anything in the Winarta reference or anywhere else. It is the type of conclusory statement that this Court has ruled does not constitute substantial evidence. *Koito*, 381 F.3d at 1152; *Cytologix Corp. v. Ventana Med. Sys., Inc*., 424 F.3d 1168, 1176 (Fed. Cir. 2005). Moreover, it is contradicted by the unrebutted testimony of Dr. Smith.

Dr. Smith explained that Winarta does not suggest any circuit arrangement or calculation method to allow measurement of a current at $W_0$ corresponding to glucose concentration. Thus, contrary to Dr. Wang's conclusory assessment, a glucose measurement could *not* be made at Winarta's $W_0$ electrode, as required by the claims. A1571-73 (¶55). Dr. Smith's testimony was unrebutted, and it directly contradicts the Board's unsupported finding that the $W_0$ electrode is "capable" of making a glucose measurement.[2]

[2] Pharmatech had the opportunity to address Dr. Smith's testimony related to Winarta in Pharmatech's Reply to LifeScan's Patent Owner's Response. Pharmatech did nothing.

Pharmatech now offers an unsupported argument that modifications of Winarta would need to be made to the meter, not the strip, in order to make a glucose measurement at $W_0$ (Ptech Br. at 60). This argument is unavailing for at least two reasons.

First, the '105 Patent claims expressly require the step of making a glucose measurement at a second working electrode. It makes no difference whether one would need to modify Winarta's strip or to modify a meter reading that strip in order to make that second glucose measurement possible. The salient point is that modification would be necessary, and there is no evidence showing that such modification would have been obvious to a person of ordinary skill in the art. It certainly is not taught or suggested by anything in Winarta, or any other art of record.

Second, for all practical purposes, Pharmatech's argument is an admission that modification of Winarta would be needed to enable a second glucose measurement. That admission directly contradicts Pharmatech's argument, and the Board's conclusion, that Winarta is "capable" of making a glucose measurement at the $W_0$ electrode. As Pharmatech now concedes, Winarta is *not* capable of doing so without modification. That modification is not taught or suggested in Winarta or any other reference, and it is nowhere identified or addressed in Pharmatech's evidence or in the Board's decision. In fact, as LifeScan explained (Br. at 46-47),

there is absolutely no evidence supporting the Board's conclusion that it was allegedly within the skill of the art to make the modifications necessary to use Winarta's $W_0$ electrode to measure glucose. Pharmatech does not, and cannot, dispute this.

As LifeScan demonstrated (Br. at 46), the three lines in Winarta that the Board *sua sponte* relied on to support its conclusion that Winarta has "circuitry for making measurements involving $W_0$" do not provide any support for the Board's finding. A26 (citing A262 (6:5-7)). Those three lines refer to measuring resistance at $W_0$, not to measuring a concentration of glucose, the same substance measured at the first electrode, W. Pharmatech again has no answer to LifeScan's point and simply ignores it.

Pharmatech argues that it was somehow *LifeScan's* burden to come forward with evidence of what modifications and additional circuitry would be needed to alter the Winarta system so that glucose measurements could be taken at the $W_0$ electrode (Ptech Br. at 60). This turns the validity analysis on its head. Pharmatech, not LifeScan, bore the burden of proving invalidity.

Pharmatech looks outside the Board's decision to find alternative evidentiary support for its conclusions. In particular, Pharmatech refers to a patent examiner's statement about Winarta, made during prosecution of a different patent application (Ptech Br. at 59 (citing A484)) and nowhere cited or relied upon by the Board. But

an examiner's erroneous opinion about Winarta's disclosure is not substantial evidence. Pharmatech also refers to Dr. Wang's testimony that the $W_0$ electrode is preferably constructed from the same material as the disclosed working electrode and can generate charge carriers (Ptech Br. at 59 (citing A517)). But making a glucose measurement, *as required by the claims*, requires not just electrodes, but corresponding circuitry. A1552-1554 (¶¶36-38). Accordingly, the only evidence Pharmatech points to is insufficient to show obviousness.

In sum, the Board's conclusions about the Winarta disclosure are based on legally erroneous analysis and are unsupported by substantial evidence.

### C. Schulman Does Not Disclose The Claimed Method Steps

Last, but not least, the Board also erred in its treatment of the Schulman reference.

The claimed method involves the use of a disposable test strip and compares multiple measurements of a sample applied to that strip. As LifeScan demonstrated (Br. at 24-26, 48-49), Schulman involves a completely different technology. The Schulman device was implanted in the patient's body and takes and compares multiple measurements of a patient's continuously flowing body fluid at different locations. The Board improperly failed to consider Schulman's disclosure as a whole, and instead cherry-picked specific claim elements from

Schulman's disclosure, while ignoring the fundamental differences between Schulman and the claimed method.

Rather than addressing the issue, Pharmatech parrots the Board's conclusions that Schulman discloses the "measuring," "comparing" and "giving an indication" steps of the '105 Patent claims (Ptech Br. at 50). It never addresses the basic point that Schulman does not disclose using a single test strip to make and compare measurements of a single sample, as the claims require. Nor does Pharmatech address LifeScan's showing that the Schulman measurements, made by separate electrode systems at different locations in the body, are akin to using *two* separate test strips to measure *two* blood samples, something very different from the claimed invention.

Pharmatech mischaracterizes this Court's precedent by suggesting that a prior art reference may be considered as anything less than a whole (Ptech Br. at 51 n.2). This is not an unresolved legal question. As this Court recently explained, "§103 does not permit a court to stitch together an obviousness finding from discrete portions of prior art references without considering the references as a whole." *In re Enhanced Sec. Research, LLC,* 739 F.3d 1347, 1355 (Fed. Cir. 2014) (citing *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1578 (Fed. Cir. 1987)).

The Board erred in failing to follow this basic and well-settled principle. In particular, the Board erred in ignoring the fundamental differences between Schulman's implantable system and the claimed method, and in cherry-picking passages from Schulman to support its obviousness rejection. This is yet another reason why the Board's obviousness determination should be reversed.

### D. There Is No Evidence Of Motivation To Combine

As discussed above and in LifeScan's Opening Brief (Br. at 39-50), the Board's findings regarding the disclosures of Nankai, Winarta, and Schulman are unsupported by substantial evidence, and for this reason alone, its decision should be reversed.

Another separate and independent reason for reversing the Board's decision is that no evidence supports the Board's finding that a person of ordinary skill in the art would have been motivated to combine the references as the Board did in reaching its conclusion. Nonetheless, Pharmatech goes to extraordinary lengths trying to find some support for the Board's findings on motivation to combine.

First, Pharmatech states, "[t]he Board credited Dr. Wang's opinion that '[o]ne of ordinary skill in the art would have been motivated to provide the indication of error based on the teachings of Nankai … and common sense'" (Ptech Br. at 53). This is not close to correct. The testimony Pharmatech quotes is from a portion of Dr. Wang's declaration addressing a combination of Nankai with

a different reference, Khazanie, not Schulman. It does not refer to the combination of references addressed by the Board. A510-512. Moreover, Pharmatech's assertion that the Board "credited" this particular testimony (about a different combination of references) mischaracterizes the Board's Final Decision. The Decision makes no reference at all to that opinion. The sum total of the testimony from Dr. Wang relied upon as purported evidence of motivation to combine Nankai with Schulman is the single, conclusory statement, "[t]his would also be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable." A510 (¶27); A20 (citing A510 (¶27)). As LifeScan has explained, such a conclusory statement is wholly inadequate as evidence to support a motivation to combine references (Br. at 50-53). *See InTouch Techs., Inc. v. VGo Commc'ns, Inc.*, 751 F.3d 1327, 1351-52 (Fed. Cir. 2014) (holding expert testimony insufficient where expert merely explained that one *could* combine references, not explaining why one *would* combine them).

Nothing else in Dr. Wang's declaration—or anywhere else—suggests that one skilled in the art would have been motivated to combine Nankai or Winarta with Schulman. Pharmatech cites a review article that was attached as an exhibit to Dr. Wang's declaration, purportedly to show his qualifications in the electrochemical glucose sensor field (Ptech Br. at 54). *See* A502 (¶3), A545, 555.

This general review article, however, is not testimony. Dr. Wang does not discuss this article in his declaration, and the Board did not cite the article anywhere in its Final Written Decision. The review article contains general, non-specific statements that are not at all probative of motivation to combine the specific references before the Board.[3] Moreover, the article is dated March 2007, years after the 2000 filing date of the '105 Patent. A546, A59. Without supporting expert testimony, the article cannot possibly evidence anything about the obviousness of the claimed invention at the relevant time period. *See InTouch Techs.*, 751 F.3d at 1352 (explaining that expert evidence must show that one of skill would have been motivated to combine references "*at the time of the invention*" (emphasis in original)).

Second, Pharmatech argues that expert testimony is not needed to prove a motivation to combine. Once again (as with the Nankai analysis, *see supra* §I.A), this is incorrect. In a case like this, where the technology is complex and beyond the grasp of an ordinary layperson, expert testimony is critical to establish motivation to combine. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1369 (Fed. Cir. 2012). This is particularly true where, as here, the prior art does not provide any teaching or suggestion to combine the references.

[3] *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (holding generic testimony unrelated to the specific combination of prior art elements insufficient to show a motivation to combine).

Here, as elsewhere, the Board erred in requiring *LifeScan* to disprove motivation to combine, rather than determining whether *Pharmatech* had met its burden on that issue. Pharmatech cannot defend the Board's reasoning on that ground. Pharmatech mistakenly places the burden on LifeScan by repeating that LifeScan failed to explain how the differences between Nankai and Schulman "would dissuade improving Nankai with Schulman's error detecting steps" (Ptech Br. at 58).[4] This is wrong because (a) as explained above, the Schulman reference must be considered *as a whole*, and not cherry-picked for the portions that match claim limitations, and (b), in any event, LifeScan provided extensive expert testimony explaining why one skilled in the art would not have combined the references relied upon by the Board. A1589- 94 (¶¶82-90).

Third, Pharmatech argues that there are a "finite number of things someone knowledgeable in the art can do with multiple samples to improve accuracy" (Ptech Br. at 56). But there is no record evidence showing this. Pharmatech's attorney argument is not evidence and should be disregarded. *Perfect Web*, 587 F.3d at 1332.

The Board's determination that one skilled in the art would have been motivated to combine the disclosures of Nankai or Winarta with Schulman is not

[4] Pharmatech did not make, and therefore waived, the same argument about the Winarta/Schulman combination.

supported by any evidence, let alone substantial evidence. For this additional, independent reason, the Decision should be reversed.

### E. The Board Erred In Ignoring Copying Evidence

The Board erred in its nexus determination and disregarded LifeScan's objective evidence. That evidence included: (a) unrebutted testimony from an expert who examined Pharmatech's test strips and concluded that "it is apparent that they are copies of the test strips illustrated and described in the '105 Patent," A1594-95; (b) unrebutted expert testimony that the strips are labeled for use with LifeScan's meters and that, when used with those meters, they carry out the steps of the '105 Patent, A1595-1596; and (c) the admission of Pharmatech's counsel that there was "no alternative design" and "if you want to have a strip that is going to work with the OneTouch Ultra system [*i.e.*, carry out the claimed method], you have to copy it," A1597; A1367 (56:20-22).

In a similar context, for purposes of commercial success, nexus is prima facie established when a patentee shows both that there is commercial success and that the thing that is commercially successful is the invention disclosed and claimed in the patent. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988); *see also Brown & Williamson Tobacco Corp. v. Phillip Morris, Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("[I]f the marketed product embodies the claimed features, and is coextensive with them, then a nexus

is presumed and the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus."). It is then the task of the challenger to adduce evidence to show that the commercial success was due to extraneous factors other than the patented invention. *See Brown & Williamson*, 229 F.3d at 1130.

The same reasoning supports a finding that nexus is prima facie established for copying where a patentee shows that there is copying and that the thing copied is the invention claimed in the patent. *See, e.g., Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1311 (Fed. Cir. 2010) ("In the absence of any record evidence attributing these secondary considerations [including copying] to causes other than the claimed invention, Crocs may rely on this added support for non-obviousness."); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008) ("[C]ommercial success *or other secondary considerations* may presumptively be attributed to the patented invention only where the marketed product embodies the claimed features, and is coextensive with them.") (emphasis added, internal quotation marks omitted).

Consistent with these cases, once LifeScan came forward with prima facie evidence of nexus, the burden then shifted to Pharmatech to produce evidence that it copied LifeScan's invention for reasons unrelated to the invention. Any other approach would impose an impossible burden on patentees to disprove all

imaginable reasons for a third party's decision to copy. *Demaco Corp.*, 851 F.2d at 1394.

Pharmatech presented no evidence that it copied LifeScan's invention for any reasons other than the merits of the invention. And it is difficult to see how it could have done so, in view of its counsel's frank admissions that Pharmatech copied the strips [recited in the patent claims] to practice the method recited in the patent claims. A1367 (56:20-24). The Board erred by finding a lack of nexus and then not giving credit to LifeScan's copying evidence as part of its obviousness analysis.

### F. LifeScan Is Not Estopped

#### 1. There Is No Collateral Estoppel

Pharmatech offers an incorrect argument that LifeScan is collaterally estopped from disputing invalidity based on the decision in *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361 (Fed. Cir. 2013) (Ptech Br. at 36-41). The Board, with good reason, did not accept that argument; it completely lacks merit.

First, the *LifeScan v. Shasta* decision did not involve a final judgment on the merits. *Shasta* was an interlocutory appeal, reversing a grant of preliminary injunction on patent exhaustion grounds. As even Pharmatech acknowledges (Ptech Br. at 39), preliminary injunction decisions typically are rendered "on the basis of … evidence that is less complete than in a trial on the merits" and

generally do not provide the benefit of a "final judicial decision based on the actual merits of the controversy." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395-96 (1981); *see also Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1007 (Fed. Cir. 2009) ("Applications for preliminary injunctions are typically presented on an abbreviated record without the benefit of a full trial."). Although not binding on this Court, the district court, on remand from the *Shasta* decision, concluded that this Court had not foreclosed LifeScan from further developing the record on patent exhaustion and that collateral estoppel did not apply. *LifeScan Scot., Ltd. v. Shasta Techs., LLC*., 2014 U.S. Dist. LEXIS 71292, *7-8 (N.D. Cal. May 23, 2014).

Second, "the issue necessarily decided" by this Court on appeal in *LifeScan v. Shasta* is far from "identical" to the validity issue presented to the Board. Pharmatech even expressly states that "[i]n *LifeScan Scotland, Ltd.*, the Court did not decide the validity issue currently before the Court" (Ptech Br. at 38). The analysis should end there. In opposing the preliminary injunction in the *LifeScan v. Shasta* case, Pharmatech and Shasta asserted, *inter alia*, that the Nankai, Winarta and Shulman references would have rendered the '105 invention obvious to a person of ordinary skill in the art. *See LifeScan, Inc. v. Shasta Techs., LLC*, 933 F. Supp. 2d 1243, 1256-59 (N.D. Cal. 2013). The district court disagreed. It found that LifeScan had "shown a likelihood of overcoming [Shasta's and Pharmatech's]

obviousness challenges." *Id.* at 1259. The district court stated that "[LifeScan] ha[s] rebutted [Shasta's and Pharmatech's] obviousness evidence with compelling evidence and argument." *Id*.

On appeal, this Court did not address—let alone disturb—the district court's findings concerning validity. Instead, the Court's decision involved issues of patent exhaustion which were not before the Board in this IPR. *LifeScan*, 734 F.3d 1361. Indeed, this Court expressly stated that it was "not reach[ing]" issues concerning the validity of the '105 Patent claims:

> "*Shasta argues that the claims of the '105 patent are invalid as obvious*. Because we conclude that LifeScan is not likely to prevail on the patent exhaustion issue, *we do not reach Shasta's validity arguments*." 734 F.3d 1370 n.3 (emphasis added).
>
> "But the question here is not whether the strips would have been separately patentable or whether the United States Patent and Trademark Office erroneously denied a patent on the strips." *Id*. at 1371.
>
> "The dissent's statements that the majority's decision 'make[s] inventiveness for exhaustion purposes coextensive with patentability,' Dissent at 8, are demonstrably inaccurate." *Id*. at 1371 n.5.

The issue this Court decided in the *LifeScan v. Shasta* case is plainly not "identical" to the obviousness issue that was before the Board here. Even Pharmatech admits this issue was not previously decided (Ptech Br. at 38). Collateral estoppel does not bar LifeScan's arguments here.

### 2. There Is No Judicial Estoppel

Equally unavailing is Pharmatech's newly-minted judicial estoppel argument—an argument it attempted to raise at the Oral Hearing, but that the Board refused to consider. A2044. Pharmatech suggests that it was unable to raise judicial estoppel to the Board because its position is based on allegedly inconsistent oral arguments made by LifeScan to the district court the very same day as the Oral Hearing. *Id.* But Pharmatech does not, and cannot, cite any such contemporaneous statements. Instead, it presents, as allegedly inconsistent positions, expert declaration statements submitted to the district court in April 2014 on remand from this Court's *Shasta* decision—*two months before* the Board hearing (Ptech Br. at 44 (citing A1680)).

In any event, judicial estoppel is inapplicable here. "'Judicial estoppel applies when a party takes a later position that is inconsistent with a former position in the same dispute, on which the party has been successful and had prevailed based on the former position.'" *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315 (Fed. Cir. 2008) (quoting *Bonzel v. Pfizer, Inc.*, 439 F.3d 1358, 1362 (Fed. Cir. 2006)).

None of the requirements for judicial estoppel are met here. First, for similar reasons as to why Pharmatech's collateral estoppel argument fails, the expert testimony that LifeScan presented to the district court relating to patent

exhaustion is in no way inconsistent with the arguments and evidence LifeScan presented to the Board in addressing the validity of the '105 Patent. The issues presented were distinct. Moreover, the evidence LifeScan presented to the district court on obviousness in its preliminary injunction motion was entirely consistent with the evidence it presented to the Board in this IPR. Pharmatech does not, and cannot, suggest otherwise. There is no "inconsistent" position. *Honeywell*, 523 F.3d at 1315.

In addition, LifeScan did not persuade the district court to accept the fact issues raised in the expert declaration (Ptech Br. at 44-45). In ruling on Pharmatech's motion for judgment on the pleadings, the district court did not address the substance of LifeScan's evidence. All it did was rule, procedurally, that the record on patent exhaustion was not closed and that judgment on the pleadings was therefore not warranted. *LifeScan*, 2014 U.S. Dist. LEXIS 71292 at *7-8. LifeScan has not presented inconsistent positions, and judicial estoppel is inapplicable.

## II. THIS COURT SHOULD RULE THAT THE BOARD WAS NOT AUTHORIZED TO INSTITUTE THIS IPR

### A. This Issue Is Properly Before The Court

The AIA authorizes only the Director or her proper delegate—not the Board—to institute IPR. This exact issue has been fully briefed and is currently

pending before the Court in *Ethicon Endo-Surgery, Inc. v. Covidien LP*, No 2014-1771 (Fed. Cir. docketed Aug. 28, 2014), and is properly before the Court here.

Contrary to Pharmatech and the PTO's assertions, 35 U.S.C. § 314(d) does not divest this Court of jurisdiction over this issue. LifeScan appealed the Board's Final Written Decision. A1. Section 314(d) does not prohibit challenges to the lawfulness of the procedure by which the Board came to its final decision. *See Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 675-76 (1986). In any event, § 314(d) only prohibits appeal of an institution decision made "by the Director." LifeScan's argument is that neither the Director nor her lawful delegate made the institution decision. Accordingly, this Court may and should reach the merits of LifeScan's argument to resolve the jurisdictional question. *See Amgen Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004).

Both Pharmatech and the PTO incorrectly argue that LifeScan waived its challenge to the PTO's procedure. But a "party need not exhaust his administrative remedies where invoking such remedies would be futile." *Associacion Columbiana de Exportadores de Flores v. United States*, 916 F.2d 1571, 1575 (Fed. Cir. 1990). 37 C.F.R. § 42.4(a) expressly delegates the Director's institution decision to the Board. Even if LifeScan had raised this issue before the PTO, the PTO was bound to follow its official regulation. *See DGR Assocs., Inc. v. United States*, 690 F.3d 1335, 1340 (Fed. Cir. 2012) (regulations

"bind the agency itself"). No mechanism exists to allow the Director to effectively immediately repeal binding regulations that govern IPRs.

In any event, this Court "retain[s] discretion to reach issues raised for the first time on appeal." *In re DBC*, 545 F.3d 1373, 1379 (Fed. Cir. 2008). Such discretion is appropriate here, where LifeScan points to a specific harm that resulted from the PTO's error—a tainted obviousness determination based on less than all of the evidence. This Court has jurisdiction to reach this issue and it should do so.

### B. The Director May Not Delegate Her Duty To Institute IPRs To The Board

The plain terms of the inter partes review (IPR) statute provide for a bifurcated process with distinct decisionmakers. Congress unambiguously defined the Director's role in that process: "[t]he Director shall determine whether to institute an inter partes review." 35 U.S.C. § 314(b). Congress was equally clear in establishing the PTAB as a quasi-independent, judicial body with members appointed directly by the Secretary of Commerce and with defined and limited roles, one of which was that the PTAB "shall … conduct each inter partes review *instituted under this chapter*." *Id.* § 316(c) (emphasis added).

35 U.S.C. § 6(b), which enumerates the duties of the PTAB, incorporates this limitation, specifying that the PTAB's duty with respect to IPRs is to "conduct

inter partes reviews … pursuant to chapter[] 31." At every turn, the IPR statute repeats that dichotomy—and never departs from it (Br. at 57-59).

Nonetheless, ignoring the mandate of the statute, the PTO purports to delegate to the PTAB—typically the same panel of the PTAB—the duties of instituting and conducting IPR proceedings. Because the PTAB's duties are limited by statute to conducting, but not instituting, IPRs, the present IPR, which was instituted by neither the Director nor her authorized delegate, is unauthorized and must be reversed.

The PTO and Pharmatech contend that the PTO may disregard the divided decision making mandate not because of anything in the text or structure of the statute, but simply because the Director, in their view, may delegate any duty to any PTO official or employee. But that view of the Director's authority fails to account for Congress's limitation of the default delegation power. Congress did not mean to include the "PTAB" when it said "Director," and the PTO may not fall back on general rules of delegation to change that—particularly where, as here, the result would contravene other basic principles of statutory interpretation, administrative law, and due process. Because of the binding nature of PTO rules, any opportunity to raise below this pure legal issue, which does not implicate the

PTAB's expertise, would have been both inappropriate and futile. This fully briefed and pressing issue is now properly before this Court for resolution.[5]

Contrary to the PTO's reframing of the issue (PTO Br. at 22, 29, 30), LifeScan's position is not that the Director must personally institute all IPRs. Rather, the Director—*or her proper delegate*—must institute IPRs. And the PTO is wrong that anyone in the PTO can be a proper delegate. The statute makes clear who, besides the Director herself, has power broad enough to make the institution decision. *See* 35 U.S.C. §§ 3(b)(1) (Deputy Director vested with authority to act in the capacity of the Director when she is absent); 3(b)(2) (Commissioner of Patents but not Commissioner of Trademarks). The statute also makes clear who the Director may herself appoint and vest with such power. *See id.* § 3(b)(3). And the statute makes clear who was not granted the power to *institute* an IPR. *See id.* § 6(b).

The Board's decision in this IPR was the result of an unlawful process that led to legal errors in its final decision. *See supra*, §I. Despite Pharmatech's failure to introduce the necessary evidence to prove that the '105 Patent is invalid, the Board's initial determination that there was a "reasonable likelihood the petitioner would prevail," A49, led to a preordained conclusion, *i.e.*, a final determination

[5] Consideration of this exact issue is currently pending before the Court in *Ethicon Endo-Surgery, Inc. v. Covidien LP*, No 2014-1771.

that Pharmatech proved invalidity by a preponderance of the evidence, A30. This is another reason why the Board's decision should be reversed.

## CONCLUSION

The final written decision of the Board should be reversed.

Dated: July 6, 2015

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Federal Circuit Rule 32(b), the undersigned hereby certifies that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B)(i) and Federal Circuit Rule 32(b).

1. Exclusive of the exempted portions of the brief, as provided in Federal Rule of Appellate Procedure 32(a)(7)(B) and Federal Circuit Rule 32(b), the brief contains 6,427 words.

2. This brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Federal Rule of Appellate Procedure 32(a)(7)(B), the undersigned has relied on the word count feature of this Microsoft Word in preparing this certificate, in addition to manually counting and adding the words included in any figures.

Dated: July 6, 2015

*/s/ Jason E. Weil*
Jason E. Weil

## CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing Reply Brief for Appellant with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system this 6 day of July, 2015, and served a copy on counsel of record by the CM/ECF system and by electronic mail.

Dated: July 6, 2015

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